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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/365,349 07/30/99 TERRY N B99-085

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EXAMINER

IBRAHIM, M

ART UNIT

PAPER NUMBER

1638

11

DATE MAILED:

10/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/365,349

Applicant(s)

Terry et al

Examiner

Medina A. Ibrahim

Group Art Unit

1638



☒ Responsive to communication(s) filed on Sep 21, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-24 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-24 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☒ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

1. In view of the appeal brief filed on 8/8/2000 and the supplemental response filed on 9/21/200, PROSECUTION IS HEREBY REOPENED. New grounds of rejections are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

- (a) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
- (b) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-3, 5-8, 13-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for transformed *Brassica juncea* expressing an *E.coli* glutamylcysteine synthetase for an improved Cd tolerance, does not reasonably provide

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enablement for any transformed plant capable of enhancing accumulation of a wide variety of heavy metals by overexpressing an ECS, and a method for decreasing heavy metal content of a medium by growing said plant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants broadly claim any plant comprising a gene from any source encoding glutamylcysteine synthetase, a transformed *Brassica juncea* with at least 50% enhanced accumulation of heavy metals, including cadmium, mercury, uranium, chromium, molybdenum, and tungsten, as compared to a corresponding wild type plant, a method for decreasing heavy metal content of any medium by growing said transformed plants, wherein the plant grows not significantly differently than the corresponding wild type plant under non-heavy metal conditions. In contrast, the specification provides guidance only for the transformation of *Brassica juncea* with the ECS gene from *E. coli* driven by double-enhanced 35S CaMV promoter, and wherein the analysis of heavy tolerance involves only in hydroponic or agar medium with Cd concentrations of 0.15- 0.25 mM of CdSO₄ (page 8 of the specification, bottom paragraph; page 9, line 15 to page 10, line 11). The specification does not set forth obtention of other plant species overexpressing exemplified or non-exemplified ECS genes for an enhanced accumulation of exemplified or non-exemplified heavy metals. No guidance has been presented for the removal of exemplified or non-exemplified heavy metals from soil, ground or industrial waste water, or other heavy metal contaminated media by the exemplified or non-exemplified transgenic plants.

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In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Noctor et al teach unpredictability of the metabolism of plant glutathione synthesis and its response to heavy metal stress conditions (see, e.g., page 623, Abstract). For example, overexpression of ECS enzyme for phytochelatin biosynthesis did not increase Cd tolerance in transgenic poplar plants grown in Cd contaminated soil (page 640, column 1, bottom paragraph). Chen et al, who teach Cd tolerance in tomato cell lines by overexpressing ECS, cite, in page 238, column 2, 3rd paragraph, two references by de Knecht et al (1992) and Delhaize et al (1989) that teach an overexpression of PCS is not responsible for increased Cd tolerance in *Silene* and *Datura* plant species respectively. Furthermore, Applicants' own specification, page 3 lines 4-9, cites another reference as late as 1999 by Goldsbrough, who teach an overexpression of ECS gene did not increase the Cd tolerance of wild type *Arabidopsis thaliana*. The publication date of Goldsbrough reference is after the priority date of the instant application, indicating the level of skill in the art even after the time of filing. Zhu et al (1999) cite, in column 2, lines 2-5, "one trait that is of great significance to phytoremediation is the ability of plants to tolerate the toxic metals from the soil". Therefore, Applicant's unexpected results, namely a transformed *Brassica juncea*

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cell line overexpressing ECS under hydroponically simulated Cd stress conditions, would not be commensurate with the scope of the claims which encompass any plant species transformed to overexpress ECS, from any source, to thereby provide an enhanced accumulation of any heavy metal from any media. Hence, given the breadth of the claims, unpredictability associated with the overexpression of ECS to induce heavy metal tolerance in any transgenic plants or plant cells, and lack of guidance as discussed above, the instant invention could not be practiced throughout the broad scope without undue trial and error experimentation .

Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims are broadly drawn to a multitude of plant species overexpressing a multitude of ECS for enhanced accumulation of a multitude of heavy metal. In contrast, the specification only provides guidance for the transformation of Brassica juncea to overexpress ECS for Cd tolerance.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide an adequate written description of the invention as broadly claimed.

See Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene or a promoter is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g a DNA

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sequence) and page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

See *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

The rejections under 35 USC 102 (a) to claims 1, 2, 5-8, 13-15, and 19 as being anticipated by Arisi et al, and under 35 USC 103(a) to claims 1-24 have been withdrawn in view of the Appeal Brief of 8 August 2000, the telephone interview between the Examiner and Applicants' representative on 19 September 2000, and the supplemental response filed by the Applicants on 21 September 2000.

Applicant's arguments filed on 21 September 2000 have been fully considered but they are not persuasive.

Applicants argue that the specification provides a list of suitable species for transformation and also provides the results of said transformation. These arguments are not persuasive.

Claims are broadly drawn to any plant which is genetically transformed to overexpress glutamylcysteine synthetase and thereby provides enhanced accumulation of any heavy metal from any medium as compared to a corresponding wild type plant, and a method of decreasing heavy metal content of any medium by growing said transgenic plant in the medium. The specification

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provides guidance only for the transformation of Brassica juncea with the ECS gene from E.coli driven by double-enhanced 35S CaMV promoter, and wherein the analysis of heavy tolerance involves only in hydroponic or agar medium with Cd concentrations of 0.15- 0.25 mM of CdSO₄ (page 8 of the specification, bottom paragraph; page 9, line 15 to page 10, line 11). The specification (see, pages 7-8, Table. 2) reveals a list of different plant species including a Brassica, Populus and Silene species , which are prophetically shown to have enhanced accumulation of a wide variety of heavy metals from a wide variety of media. However, Goldsbrough, Noctor et al, and de Knecht et al each has separately shown that an overproduction of ECS or PCS in Brassica, Populus and Silene species respectively did not increase heavy metal tolerance. Neither the prior art nor the present disclosure establishes a predictable relationship between heavy metal tolerance and overexpression of ECS or PCs in any transgenic plant species. Therefore, given the breadth of the claims which encompass any plant which is genetically transformed to overexpress glutamylcysteine synthetase and thereby provides enhanced accumulation of any heavy metal from any medium as compared to a corresponding wild type plant, the uncertain and unpredicatble relationship cited in Applicants' response of 08/01/2000 and in the Appeal Brief , and lack of guidance as described above , the instant claimed subject matter can not be practiced by one skilled in the art without undue experimentation.

The following Examiner's Amendment, proposed on 19 September 2000, was not approved by Applicants' representative.

IN THE CLAIMS:

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In Claim 1, insert ---Brassica--- before "plant".

Cancel claim 3.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The examiner can normally be reached on Monday-Tuesday, and Thursday from 7:30 AM to 6:30 PM.

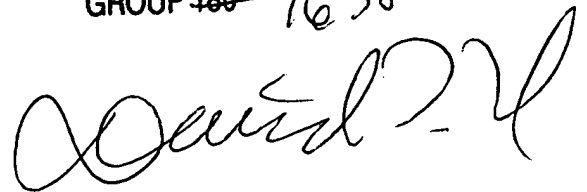
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

October 19, 2000

mai

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

A handwritten signature in cursive script, appearing to read "David T. Fox", written over the printed name and title.